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BETHESDA, MD

JUNE 23-25, 2004



ADVANCES IN HEALTH OUTCOMES MEASUREMENT

Exploring the Current State and the Future Applications of Item Response Theory, Item Banks, and Computer-adaptive Testing

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OVERVIEW

Outcomes measurement is an integral part of assessing the effectiveness and cost effectiveness of healthcare interventions and specific treatments. This includes assessing the implications of such things as: changes in health policy, introduction of a new pharmaceutical or medical device, insurance coverage and reimbursement decisions, and community lifestyle change interventions. The techniques and methods for measuring health outcomes, particularly for patient-reported outcomes (PROs), are evolving and becoming increasingly sophisticated. This conference provides a forum for attendees to learn about the latest advances in item response theory (IRT). The benefits and limitations of IRT modeling, the application of these methods to improve PRO questionnaires, the feasibility and mechanisms for developing item banks, and the utility of computerized adaptive testing (CAT) for measuring health outcomes will be explored in detail. The major aims of the conference are to illustrate how IRT can be used to improve the science of PROs measurement related to health-related quality-of-life and health behaviors. Of special interest will be a focus on the future of health outcomes measurement, especially in regard to: the feasibility of public-domain item banks and CATs, uses in observational and clinical studies, application to clinical practice, and the role public and private entities can play in this effort. Session topics will include:

- Traditional versus modern approaches to health outcomes measurement
- ▶ Applications of IRT modeling for:
 - Building and refining outcome and behavioral science measures
 - Assessing measurement equivalence: differential item functioning (DIF)
 - Comparing or combining scores from multiple instruments: instrument linking/equating
 - Developing health outcome item banks
- Computerized adaptive testing (CAT) for health outcomes measurement
- ▶ Mapping a research agenda for health outcomes measurement in the future

Each session will provide time for audience participation.

TUTORIAL

Item Response Theory (IRT) and Application Section Improving Health Outcomes Measurement

June 23, 2004, 1:0 - 0) 3 n

INSTRUCTOR: Steven. Reise, PhD, Professor of Measurement and Psychometrics, Department of Psychology, UCLA

For preliminary content and related information, please visit the NCI conference website.

http://www.outcomes.cancer.gov/conference/irt

HEALTH OUTCOMES RESEARCH COMMITTEE

Jakob B. Bjorner, MD, PhDDeputy Chief Science Officer
QualityMetric Inc.

David Cella, PhD

Professor, Northwestern University Feinberg School of Medicine; Director, Center on Outcomes Research and Education

Chih-Hung Chang, PhD

Assistant Professor Northwestern University

Ron D. Hays, PhD

Professor, UCLA, Senior Scientist, RAND

Colleen A. McHorney, PhD

Professor, Indiana University School of Medicine; Senior Scientist, Regenstrief Institute, Inc.

Eleanor M. Perfetto, PhD, MS

President, Drug Information Association THE WEINBERG GROUP INC.

Bryce B. Reeve, PhD

Psychometrician, National Cancer Institute Conference Coordinator

BEHAVIORAL SCIENCE COMMITTEE

Tom Baranowski, PhD

Professor, Baylor College of Medicine

Louise C. Mâsse, PhD

Psychometrician, National Cancer Institute Conference Coordinator

Russ Pate, PhD

Professor, University of South Carolina

Ken Resnicow, PhD

Professor, University of Michigan

TARGET AUDIENCE

- Health outcomes researchers
- Quality-of-life researchers
- Psychometricians
- Survey developers
- Clinicians
- Market researchers
- Health behavior scientists
- Behavioral nutritionists or kinesiologists
- ► Health promotion researchers
- Healthcare professionals
- Pharmaceutical industry
- Regulatory affairs professionals

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CONTINUING EDUCATION Tutorial: 286-999-04-013-L04; 3.5 category 1 credits/contact hours (.35 CEUs); .4 IACET CEUs CREDIT ALLOCATION Conference: 286-999-04-012-L04; 13.5 category 1 credits/contact hours (1.35 CEUs); 1.4 IACET CEUs

Conference Learning Objectives: At the conclusion of this meeting, participants should be able to:

- Discuss the benefits and limitations of the traditional and modern measurement approaches for health outcomes and behavioral science measurement
- Describe the various approaches (both IRT and non-IRT) to evaluating measurement equivalence
- Discuss the various approaches to linking two or more scales onto a common metric for either cross-walking or combining scores
- Describe and recommend the methodological steps for evaluating the psychometric properties of survey data
- Identify the critical issues involved with developing and maintaining item banks and computerized adaptive tests
- Discuss the potentials and challenges of using computerized adaptive tests in observational and clinical studies

Tutorial Learning Objectives: At the conclusion of this tutorial, participants should be able to:

- Describe the advantages of using item response theory modeling over classical test theory methods to evaluate and develop tailored instruments
- Interpret IRT characteristic and information functions
- Discuss how patient reported outcomes measurement will benefit from the various applications of IRT modeling

WEDNESDAY • JUNE 23

TUTORIAL REGISTRATION 12:00-1:00 PM

TUTORIAL 1:00-5:00 PM

ITEM RESPONSE THEORY (IRT) AND APPLICATIONS OF IRT FOR IMPROVING HEALTH OUTCOMES MEASUREMENT **INSTRUCTOR**

Steven P. Reise, PhD

Professor of Measurement and Psychometrics, Departs of Psychology UCLA

This introductory workshop egin with a discussion of the basics (RT) modeling, including discussions of of item respa parameters, model assumptions, item and test characterists and information curves, frequently used IRT models, and differences between traditional and IRT methods. The course will discuss the role of IRT modeling in health outcomes research of evaluating and developing questionnaires, identifying differential item functioning, linking instruments, developing item banks, and assessing change. Critical issues for applying this methodology in health outcomes research will be discussed.

CONFERENCE REGISTRATION 4:00-5:00 PM

THURSDAY • JUNE 24

REGISTRATION AND 7:00-8:00 AM CONTINENTAL BREAKFAST

WELCOME AND OPENING REMARKS 8:00-8:20 AM

Ron D. Hays, PhD

Professor, DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA; Senior Scientist, RAND CORPORATION

8:20-8:40 AM **CONFERENCE CHARGE**

Joseph Lipscomb, PhD

Chief, Outcomes Research Branch, NATIONAL CANCER INSTITUTE Eleanor M. Perfetto, PhD, MS

President, DRUG INFORMATION ASSOCIATION;

THE WEINBERG GROUP, INC.

8:40-9:20 AM

THE SCIENCE OF HEALTH OUTCOMES MEASUREMENT

This session will review the current state of the science in health outcomes measurement. What defines a "quality" or psychometrically strong measure? What are the limitations of the instruments we use today? Are we satisfied with the analytical tools used to evaluate our measures?

Neil K. Aaronson, PhD

Head, Division of Psychosocial Research and Epidemiology, THE NETHERLANDS CANCER INSTITUTE

9:20-10:10 AM

THE TRADITIONAL AND MODERN APPROACHES TO OUTCOMES MEASUREMENT

This session will define and contrast both the traditional approach (i.e., CTT) and the modern measurement (i.e., IRT) approach for data analysis and scoring. Also, it will discuss the limitations and strengths of these methods in health outcomes measurement.

Ronald K. Hambleton, PhD

Distinguished University Professor, School of Education, University of Massachusetts at Amherst

10:10-10:40 AM REFRESHMENT BREAK

10:40-11:40 AM

BUILDING AND REVISING OUTCOME MEASURES: EVALUATING ITEM AND SCALE FUNCTIONING WITH THE IRT MODEL

This session will discuss how IRT may be used both to evaluate item and scale properties and to inform questionnaire revisions. What added information do we learn about the response data from IRT modeling?

Bryce B. Reeve, PhD

Psychometrician, Outcomes Research, NATIONAL CANCER INSTITUTE

Maria Orlando, PhD

Behavioral Scientist, RAND CORPORATION

11:40 AM-1:00 PM

ASSESSING MEASUREMENT EQUIVALENCE ACROSS POPULATIONS: DIFFERENTIAL ITEM FUNCTIONING (DIF)

This session will discuss the importance for evaluating DIF for determining measurement equivalence of item content across instruments administered to different populations (differing by race, age, gender, etc.) or instruments administered in different languages. How will DIF assessment benefit health disparities research?

Jeanne A. Teresi, EdD, PhD

Senior Research Associate, COLUMBIA UNIVERSITY

Leo S. Morales, MD, PhD

Assistant Professor, DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA; Behavioral Scientist, RAND CORPORATION

John A. Fleishman, PhD

Senior Social Scientist, Center for Financing Access and Cost Trends, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

1:00-2:20 PM LUNCHEON AND REVIEW POSTERS

2:20-3:00 PM

COMPARING OR COMBINING SCORES FROM MULTIPLE INSTRUMENTS: INSTRUMENT LINKING (EQUATING)

This presentation will address several issues associated with the linking of health outcomes. What is meant by outcomes linking and equating? How does equating differ from other types of linking? What common data collection designs are used to capture data for outcomes linking? What are some of the standard statistical procedures used to link outcomes directly? What assumptions do they make? What role does IRT play in linking outcomes? What assumptions do IRT methods make? Illustrations of different kinds of linkages will be provided.

Neil J. Dorans, PhD

Principal Measurement Statistician in the Research & Development Division, EDUCATIONAL TESTING SERVICE

3:00-4:45 РМ

DEVELOPING TAILORED INSTRUMENTS: ITEM BANKING AND COMPUTERIZED ADAPTIVE ASSESSMENT

This session will discuss the critical role that IRT plays to develop the item bank and why CTT methods are inappropriate for such a task. What challenges/decisions will we have to make in choosing both the appropriate IRT model and the constructs we want to measure? How can we balance the assumptions of the unidimensional IRT models with the multifaceted nature of the constructs measured in health outcomes research?

Chih-Hung Chang, PhD

Assistant Professor, NORTHWESTERN UNIVERSITY

Jakob B. Bjorner, MD, PhD

Deputy Chief Science Officer, QUALITYMETRIC INCORPORATED David Thissen, PhD

Professor, Quantitative Program, Department of Psychology, University of North Carolina at Chapel Hill

4:45-5:45 рм

RECEPTION AND POSTER SESSION

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FRIDAY • JUNE 25

7:00-8:00 AM

REGISTRATION AND
CONTINENTAL BREAKFAST

8:00-10:00 AM THE IRT DATA ANALYSIS PROJECTS

In parallel sessions, two research teams will demonstrate the strengths and challenges of applying IRT modeling for evaluating data in health outcomes research and behavioral science. The sessions will provide detailed examples of the logic and flow of analyses, the tackling of technical problems, and the interpretation of results. Examples of input and output files along with analysis summaries will be provided to the audience.

8:00-10:00 AM PARALLEL SESSION A

Demonstration of item and scale analysis, differential item functioning, instrument linking, and item banking using data collected on four HRQOL questionnaires.

RESEARCH TEAM

Karon F. Cook, PhD (Team Leader)

Associate Director of Research, Parkinson's Disease Research, Education, and Clinical Center, HOUSTON VA MEDICAL CENTER

Cayla R. Teal, PhD (Team Leader)

Postdoctoral Fellow, Houston Center Quality of Care and Utilization Service, HOUSTON VA MEDICAL CENTER

Jakob B. Bjorner, MD, PhD

Deputy Chief Science Officer, QUALITYMETRIC INCORPORATED David Cella, PhD

Professor of Psychiatry and Behavioral Science, NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE; Director, CENTER ON OUTCOMES RESEARCH AND EDUCATION

Chih-Hung Chang, PhD

Assistant Professor, NORTHWESTERN UNIVERSITY

Paul K. Crane, MD, MPH

Acting Instructor, University of Washington



Laura E. Gibbons, PhD

Research Scientist, University of Washington

Ron D. Hays, PhD

 ${\it Professor}, \ {\it David Geffen School of Medicine at UCLA};$

Senior Scientist, RAND CORPORATION

Colleen A. McHorney, PhD

Professor, Indiana University School of Medicine

Senior Scientist, REGENSTRIEF INSTITUTE, INC.

Katja Ocepek-Welikson, MPhil

HEBREW HOME FOR THE AGED IN NEW YORK CITY

Anastasia E. Raczek, PhD

Scientist, QUALITYMETRIC INCORPORATED

Bryce B. Reeve, PhD

Psychometrician, Outcomes Research,

NATIONAL CANCER INSTITUTE

Jeanne A. Teresi, EdD, PhD

Senior Research Associate, COLUMBIA UNIVERSITY

8:00-10:00 AM PARALLEL SESSION B

Three presentations using Behavioral Consortium data to illustrate IRT applications.

RESEARCH TEAM

Louise C. Mâsse, PhD

Psychometrician, Behavioral Research Program,

NATIONAL CANCER INSTITUTE

Mark R. Wilson, PhD

Professor, Graduate School of Education,

University of California, Berkeley

Diane D. Allen

Graduate Student Researcher

University of California, Berkeley

DISCUSSANTS

Steven P. Reise, PhD

Professor of Measurement and Psychometrics

Department of Psychology, UCLA

Ken Resnicow, PhD

Professor, University of Michigan

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM

THE FUTURE OF OUTCOMES MEASUREMENT: ITEM BANKING, TAILORED SHORT FORMS, AND COMPUTERIZED-ADAPTIVE ASSESSMENT

This session will discuss how computerized-adaptive testing (CAT) will revolutionize the way we measure outcomes through the development of tailored short forms and computerized-adaptive tests. Dr. Cella and Dr. Ware will present results from their own work and discuss how item banking (short forms and CATs) will benefit the measurement of patient-reported outcomes in observational studies, clinical trials, and clinical practice.

David Cella, PhD

Professor of Psychiatry and Behavioral Science, Northwestern University Feinberg School of Medicine; Director, Center on Outcomes Research and Education

John E. Ware, PhD

Chief Executive Officer and Chief Science Officer, QUALITYMETRIC INCORPORATED

12:00-1:15 PM LUNCHEON

1:15-3:15 PM

CRITICAL ISSUES FOR DEVELOPING AND MAINTAINING ITEM BANKS AND CATS – BRINGING THE CONCEPT INTO REALITY: THE IDEA OF A NATIONAL ITEM BANK

This session will discuss the feasibility for developing and implementing item banks and CATs in observational and clinical settings. What critical issues should we address and how can we overcome the barriers to issues like proprietary rights? What are the costs and amount of work that are required to create these products? What role should government (e.g., NIH, FDA) and private entities play in this effort?

Colleen A. McHorney, PhD

Professor, Indiana University School of Medicine; Senior Scientist, Regenstrief Institute, Inc.

Jeff A. Sloan, PhD

Lead Statistician and Chair of Quality of Life Research Committee, MAYO CLINIC, ROCHESTER

Dennis A. Revicki, PhD

Director, Center for Health Outcomes Research and Senior Research Leader, MEDTAP INTERNATIONAL; Adjunct Professor, Department of Psychiatry, GEORGETOWN UNIVERSITY MEDICAL SCHOOL.

Lawrence J. Fine, MD, DrPH

Medical Advisor, Office of Behavioral and Social Sciences Research, NATIONAL INSTITUTES OF HEALTH

Robert T. O'Neill, PhD

Director, Office of Biometrics, CDER, FDA

Laurie Beth Burke, RPh, MPH

Director, Study Endpoints and Label Development, Office of New Drugs, CDER, FDA

3:15-3:30 PM REFRESHMENT BREAK

3:30-5:00 РМ

NEXT STEPS IN HEALTH OUTCOMES AND BEHAVIORAL SCIENCE

For both health outcomes and behavioral researchers, speakers will make recommendations for how their field of study will benefit by incorporating the methods discussed over the past two days. What demonstrations are necessary to explore the potential benefits of item banking and CATs to health outcomes measurement? What role should academia, industry, and government play to push this arena forward?

Ron D. Hays, PhD

Professor, DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA; Senior Scientist, RAND CORPORATION

Margaret Rothman, PhD

Executive Director, Health Economics Johnson & Johnson

Joseph Lipscomb, PhD

Chief, Outcomes Research Branch, NATIONAL CANCER INSTITUTE

Peter M. Fayers, PhD

Professor of Medical Statistics,

University of Aberdeen Medical School

5:00 PM CONFERENCE ADJOURNED

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Audio/visual taping of any DIA workshop is prohibited without prior written consent from DIA.

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Reduced Rate: Single \$200 Double \$225 Government Rate: Single \$150 Double \$175

To reserve your room, please contact the Hyatt Regency Bethesda by telephone at +1-301-657-1234 or +1-800-233-1234, and mention the DIA meeting. The Hyatt Regency Bethesda is located at One Bethesda Center, Bethesda, MD 20814, USA.

CONTACT INFORMATION

For meeting information, contact Cherese Verdi, Meeting Manager at the DIA office in Horsham, PA by telephone +1-215-442-6131, fax +1-215-442-6199 or email Cherese. Verdi@diahome.org.

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